



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

October 2, 2000

Donald O. Beers  
Arnold & Porter  
555 Twelfth Street, NW  
Washington, DC 20004-1206

Dear Mr. Beers:

Your petition submitted on behalf of Glaxo Welcome Inc., asking the Food and Drug Administration to decline to approve any new or pending abbreviated new drug application for any generic cefuroxime axetil product that contains cefuroxime axetil in crystalline form, was received by this office on 09/29/00. It was assigned docket number 00P-1550/CP 1 and it was filed on 9/29/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

  
Gloria Ortega  
Dockets Management Branch

00P-1550

ACK 1